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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/710,778	08/02/2004	Muhammed Majeed		4777

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SABINSA CORPORATION
70 ETHEL ROAD WEST
UNIT 6
PISCATAWAY, NJ 08854

EXAMINER
LEITH, PATRICIA A

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 06/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/710,778	MAJEED ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 August 2004* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-10 are pending in the application and were examined on their merits.

Specification

The specification is objected to for the following reasons:

Applicant has cited the term 'Methothrexate'. It is believed that Applicant intends for this to read 'Methotrexate'.

The Specification also does not contain page numbers. Correction is necessary.

Paragraphs 15, 18, 20, 24, 35, 36, 37, 39 –42, 44, 48 and 54 do not contain a period at the end of the paragraph.

The use of the trademarks Methotrexate and Boswellin has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The use of the trademark Boswellin is capitalized and accompanied by the generic terminology.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 states a method *and* a composition. Claims should only be directed toward a composition *or* a method respectively. Applicant is asked to amend the claims to recite a method or composition only, and then add a new independent claim stating the remaining composition or method. Please note that claim dependencies will need to be amended accordingly. An easy method of changing the claims would be to cancel all existing claims and add new claims pertaining to compositions and methods separately.

Claims 1 and 2 fail to point out what is included or excluded by the claim language. These claims are omnibus type claims and are thus are indefinite. It is

suggested that the limitations of claims 2 and 3 be incorporated into claim 1 in order to overcome this rejection.

Claim 9 states 'or other dosage forms'. The meets and bounds of this phrase cannot be clearly delineated because it cannot be absolutely determined what Applicants intend to include or exclude by recitation of the word 'other'. Correction is necessary.

Because claims 3-8 depend either directly or indirectly upon claims 1-2, these claims necessarily possess all of the limitations of either claims 1 or 2 and are therefore also deemed indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating Psoriasis, does not reasonably provide enablement for treatment of any hyperproliferative skin conditions. The specification does not enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Inventions targeted for human therapy bear a heavy responsibility to provide supporting evidence because of the unpredictability in biological responses to therapeutic treatments. The standard of enablement is higher for such inventions

because effective treatments for disease conditions are relatively rare, and may be unbelievable in the absence of strong supporting evidence. Claims drawn to pharmaceutically acceptable compositions and to methods of administering compounds to humans generally require supporting evidence because of the unpredictability in biological responses to therapeutic treatments.

The Instant claims are broad enough to encompass skin disease such as malignant skin cancer.

Wands requires that one consider the number of working examples presented in the instant specification. It is noted that there in not a single example in the instant specification, working or prophetic, wherein the composition of the claims will work beneficially on any type of skin cancer. whose amino acid sequence deviates from nature. Since there are **no** working examples, then one must consider the guidance provided by the instant specification and the prior art of record.

The instant specification provides absolutely no guidance as to what types of skin cancer could be treated with the composition of the Instant claims, how this would occur, or why one would expect this to occur. No nexus has been established between the treatment of psoriasis, and the treatment of potentially life-threatening malignant skin cancer. Thus, the instant specification provides no working examples and no guidance that would permit and artisan to practice the invention commensurate with the scope of the instant claims.

The prior art makes clear that treatment of skin cancer is difficult and compositions which have any therapeutic effect on skin cancer are rare; the patient often needing surgery to remove malignant tissues (see for example, Cummins, 2006 entire reference).

In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that:

> "Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, **he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art**; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved." (emphasis added)

The inadequate disclosure coupled with a lack of representative examples and the art recognized unpredictability with respect to hyperproliferative skin conditions such as skin cancer thus preclude the use of the Instantly claimed composition for treatment of any disease besides psoriasis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over BANERJEE et al. (WO003080092A1, 2003) in view of Pera (US 20020148478 A1) in view of Yegorova (US 20020176900 A1).

It is noted that these claims were examined as if they were directed toward two separate sets of claims, one directed toward the composition, and one directed toward the method. In the Instant case, the method claims are free of the art, but please note 112 First rejections over the scope of these claims *supra.* If claims are amended to recite a method for treating psoriasis with the composition as recited in claim 3 (as well as amended to overcome 112 Second rejections) the claims may be allowable.

Banerjee et al. (WO003080092A1, 2001) teaches that the gum resin exudate of Boswellia serrata is useful for treating arthritis (see Abstract).

Banerjee et al. did not specifically teach wherein a selenium compound was added to the composition comprising Boswellia serrata for treatment of arthritis. Nor does Banerjee et al. teach wherein the composition comprises the specific amounts required by the claims (e.g., claim 6) or wherein the composition was administered topically.

Pera (US 20020148478 A1) specifically states that "selenium helps prevent or relieve arthritis" (see [0136]).

Yegorova (US 20020176900 A1) states that "Selenomethionine is the most bioavailable form of selenium" (see [0052]).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for treating arthritis. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518. Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

It is noted that although Pera did not specifically teach that selenomethionine was useful for treating arthritis, it is clear from Yegorova that selenomethionine for example, is a bioavailable form of selenium. Thus, one of ordinary skill in the art would have been motivated to substitute selenomethionine for selenium in order to create a composition which was more readily bioavailable and hence more therapeutically active than selenium.

Although none of the references specifically taught wherein the composition was used topically, it is deemed that topical routes of administration in order to deliver pharmaceutical compositions systemically were routine in the art at the time the invention was made. One of ordinary skill in the art would have been motivated to make a topical form of the composition in order to give patients a choice of administration routes.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Thursday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1655

April 26, 2006